

AUG 26 2004

K041846  
510(k) SUMMARY  
MINRAD INC.  
SabreSource™ Drape

**Submitter's Name, Address, Telephone Number, Contact Person  
and Date Prepared**

**Contact Person**

John McNeirney  
MINRAD INC.  
847 Main Street  
Buffalo, NY 14203  
Phone: (716) 855-1068  
Facsimile: (716) 855-1078

**Date Prepared**

December 19, 2003

**Name of Device and Name/Address of Sponsor**

SabreSource™ Drape  
MINRAD INC.  
847 Main Street  
Buffalo, NY 14203

**Device Name**

Trade Name:	SabreSource™ Drape
Common Names:	Equipment Cover, Equipment Drape
Classification Name:	Light Beam Patient Position Indicator Accessory Surgical Drape and Drape Accessories

**Predicate Devices**

- 1) Microtek Medical, Inc. – Large C-Arm Drape Product Number 4982
- 2) Contour Fabricators Number CFI-600, equipment drape
- 3) MINRAD INC. – DRTS™ Drape

**Intended Use**

The SabreSource™ Drape is intended to help prevent contamination of the SabreSource™ device when used in the operating room or other surgical environments.

**Technological Characteristics and Substantial Equivalence**

The SabreSource™ Drape is a sterile plastic bag to cover the SabreSource™ Targeting System. The drape contains an optically clear window shaped like a section of a hemisphere with a 30 cm radius that will allow undistorted transmission of the laser beam from the SabreSource™ to the patient. Any dimensional or design differences between the SabreSource™ Drape and the predicate devices are minor and raise no new issues of safety or effectiveness.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**AUG 26 2004**

Mr. John McNeirney  
Vice President and CTO  
MINRAD, Inc.  
847 Main Street  
BUFFALO NY 14203

Re: K041846  
Trade/Device Name: SabreSource™ Drape  
Model 301900  
Regulation Number: 21 CFR 878.4370  
Regulation Name: Surgical drape and  
drape accessories  
Regulatory Class: II  
Product Code: 79 KXX  
Dated: July 28, 2004  
Received: July 30, 2004

Dear Mr. McNeirney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

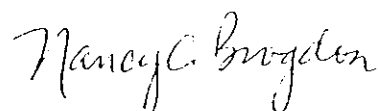
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

**SabreSource™ Drape**  
**Indications for Use Statement**

K041846

**510(k) Number (if known):**

This is an initial submission; no 510(k) number has been issued.

**Device Name:**

SabreSource™ Drape

**Indications for Use:**

The SabreSource™ Drape is to be used in an operating room environment to cover the SabreSource™ device when it is mounted on an x-ray machine for procedures wherein it is deemed desirable to protect the SabreSource™ device from contamination with patient fluids or liquids.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER  
PAGE IF NEEDED)

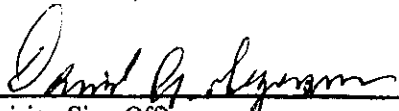
\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒  
(Per 21 C.F.R. 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number

K041846